August 11, 2021

Eyenovia Reports Second Quarter 2021 Financial Results

Announced positive topline data from its Phase 3 VISION-1 study evaluating MicroLine for the treatment of presbyopia

Company on track to initiate second Phase 3 presbyopia trial, VISION-2, by year-end 2021

MydCombi PDUFA date confirmed for October 28, 2021

Company to host conference call and webcast today, August 11, at 4:30pm ET

NEW YORK, Aug. 11, 2021 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on its proprietary microdose array print (MAP™) platform technology, today announced its financial and operating results for the second quarter ended June 30, 2021.

Second Quarter 2021 and Recent Business Highlights

- Announced positive topline data from the company's Phase 3 VISION-1 clinical trial of its proprietary presbyopia therapy, MicroLine.
  Select data highlights include:
  - Subjects treated with MicroLine 2% were 7.7 times more likely to achieve the primary endpoint of 3-line or greater improvement in near vision as compared to placebo (Odds Ratio=7.7; statistically significant difference $p<0.05$).
  - 71% of patients reported a meaningful improvement in near vision according to an exit survey conducted by study investigators.
  - MicroLine had a favorable safety profile, with no serious adverse events and fewer than 3% of study participants reporting headache (including brow ache), instillation discomfort or moderate hyperemia.
- Based on the positive results from the VISION-1 trial, the company is advancing plans to initiate a second Phase 3 trial of MicroLine, VISION-2, by year end 2021.
- PDUFA date from the Company's pupil dilation agent, MydCombi™, confirmed for October 28, 2021.
- Participated in a panel discussion on presbyopia at Eyecelerator 2021
- Participated in the Ladenburg Thalmann 2021 Healthcare Conference and the William Blair Biotech Focus Conference 2021

Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia, commented, "We are pleased to report another productive quarter for Eyenovia. The recently announced positive topline data from our Phase 3 VISION-1 trial of MicroLine in presbyopia highlights the impressive potential of our ophthalmic and Optejet® platform. With compelling efficacy and tolerability in patients, MicroLine, if approved, could become a promising new alternative for patients who desire a temporary, on demand alternative to reading glasses, particularly in indoor or low light conditions, a clear differentiator versus many other

presbyopia therapeutics in development. We continue to anticipate initiating a second Phase 3 trial, VISION-2, by the end of the year, and anticipate topline data in mid-2022.

“We are actively preparing for our MydCombi PDUFA date, which has been confirmed for October 28 of this year. We believe MydCombi, our mydriatic candidate, has the potential to become the new standard of care for the approximately 100 million comprehensive eye exams conducted every year in the U.S. alone.

“The MicroLine and MydCombi programs, together with MicroPine, which we have out-licensed to Bausch Health and Arctic Vision for up to $100 million in potential development milestones, compose our late-stage pipeline with three promising candidates and a potential approval as early as October. We look forward to providing updates on our progress during the remainder of the year,” Dr. Ianchulev concluded.

Second Quarter 2021 Financial Review

For the second quarter of 2021, net loss was approximately $4.8 million, or $(0.19) per share, compared to a net loss of approximately $5.0 million, or $(0.25) per share, for the second quarter of 2020.

For the second quarter of 2021, the Company reported license fee revenue from its Arctic Vision license agreement of $2.0 million and a corresponding cost of revenue representing payments to Senju of $800,000.

Research and development expenses for the three months ended June 30, 2021 totaled $3.6 million, an increase of 24%, as compared to $2.9 million recorded for the three months ended June 30, 2020.

For the second quarter of 2021, general and administrative expenses totaled $2.3 million, an increase of 12%, as compared to $2.1 million recorded for the three months ended June 30, 2020.

Total operating expenses for the second quarter of 2021 were approximately $6.0 million, compared to total operating expenses of approximately $5.0 million for the same period in 2020, an increase of approximately 19%.

As of June 30, 2021, the Company’s cash balance was approximately $27.2 million. This includes $7.5 million of net proceeds received from the previously announced credit facility of up to $25 million through Silicon Valley Bank (SVB). The remaining two tranches ($7.5 million and $10.0 million in gross proceeds) will be available to the Company subject to the satisfaction of certain milestones and covenants as outlined in the credit agreement.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30pm ET on Wednesday, August 11, 2021. Participants should dial 855-327-6837 (domestic) or 631-891-4304 (international) with the conference code 10015927. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.eyenovia.com.

After the live webcast, the event will be archived on Eyenovia’s website for one year.

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more information, visit www.eyenovia.com.

The Eyenovia Corporate Information slide deck may be found at ir.eyenovia.com/events-and-presentations.

About MicroLine for Presbyopia

MicroLine is a pharmacologic treatment for presbyopia. Presbyopia is the non-preventable, age related hardening of the lens, which causes a gradual loss of the eye's ability to focus on nearby objects and is estimated to affect nearly 113 million Americans. Current treatment options are typically device-based, such as reading glasses and contact lenses. Pilocarpine ophthalmic solution is known to constrict the pupil and improve near-distance vision by creating an extended depth of focus through its small aperture effect. Eyenovia believes that its administration of pilocarpine using the Company's high precision microdosing technology could provide a meaningful improvement in near vision while enhancing tolerability and usability.

About MicroPine for Progressive Myopia

MicroPine (atropine ophthalmic solution) is Eyenovia's investigational, potentially first-in-class topical treatment for the reduction of pediatric myopia progression, also known as nearsightedness, in children ages 3-12. It has been developed for comfort and ease-of-use in children, and its microdose administration is designed to potentially result in low systemic and ocular drug exposure. MicroPine has been licensed to Bausch Health Companies, Inc. in the United States and Canada, and Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

About MicroStat (MydCombi™) for Mydriasis

MydCombi is Eyenovia's first-in-class fixed-combination micro-formulation product (tropicamide 1% - phenylephrine 2.5%) candidate for pharmacologic mydriasis (eye dilation), which is targeted to improve the efficiency of the estimated 100 million office-based comprehensive eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. Developed for use without anesthetic, Eyenovia is developing MicroStat to help improve the efficacy and tolerability of pharmacologic mydriasis.

About Optejet® and Microdose Array Print (MAP™) Therapeutics

Eyenovia's Optejet microdose formulation and delivery platform for ocular therapeutics uses high-precision piezo-print technology to deliver 6-8 µL of drug, consistent with the capacity of the tear film of the eye. We believe the volume of ophthalmic solution administered with the Optejet is less than 75% of that delivered using conventional eyedroppers, thus reducing overdosing and exposure to drug and preservatives. Eyenovia's patented microfluidic ejection technology is designed for fast and gentle ocular surface delivery, where solution is dispensed to the ocular surface in approximately 80 milliseconds, beating the ocular blink reflex. Successful use of the Optejet has been demonstrated more than 85% of the time after basic training in a variety of clinical settings compared to 40 – 50% with conventional

eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

Forward-Looking Statements

Except for historical information, all of the statements, expectations and assumptions contained in this press release are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions, including estimated market opportunities for our product candidates and platform technology. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and in some cases are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in documents which we file with the U.S. Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to, among other things: risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could still be adversely impacted by COVID-19 and resulting social distancing), timing, progress and results of such trials; the timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our product candidates; the potential impacts of COVID-19 and related economic disruptions on our supply chain, including the availability of sufficient components and materials used in our product candidates; the potential advantages of our product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; intellectual property risks; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; and our competitive position. Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.

Eyenovia Contact:
Eyenovia, Inc.
John Gandolfo
Chief Financial Officer
jgandolfo@eyenovia.com

Eyenovia Investor Contact:
Eric Ribner
LifeSci Advisors, LLC
eric@lifesciadvisors.com
(646) 751-4363

Eyenovia Media Contact:
Sam Choinski
Pazanga Health Communications

schoinski@pazangahealth.com
(603) 489-5964

EYENOVIA, INC.

Condensed Balance Sheets

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 27,176,843	$ 28,371,828
Deferred license costs	-	1,600,000
License fee and expense reimbursements receivables	899,332	2,966,039
Prepaid expenses and other current assets	1,418,834	453,478
Total Current Assets	29,495,009	33,391,345
Property and equipment, net	968,881	396,380
Security deposit	119,035	119,035
Total Assets	$ 30,582,925	$ 33,906,760
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,667,634	$ 1,461,665
Accrued compensation	870,666	1,150,672
Accrued expenses and other current liabilities	1,054,923	1,480,692
Deferred rent - current portion	6,857	7,809
Deferred license fee	10,000,000	14,000,000
Notes payable - current portion	959,763	97,539
Total Current Liabilities	14,559,843	18,198,377
Deferred rent - non-current portion	37,632	38,684
Notes payable - non-current portion	6,994,893	365,814
Total Liabilities	21,592,368	18,602,875
Commitments and contingencies		
Stockholders' Equity:		

Preferred stock, $0.0001 par value, 6,000,000 shares authorized;		
0 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized;		
25,946,646 and 24,978,585 shares issued and outstanding		
as of June 30, 2021 and December 31, 2020, respectively	2,595	2,498
Additional paid-in capital	96,621,948	92,742,306
Accumulated deficit	(87,633,986)	(77,440,919)
Total Stockholders' Equity	8,990,557	15,303,885
Total Liabilities and Stockholders' Equity	$ 30,582,925	$ 33,906,760

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating Income				
Revenue	$ 2,000,000	$ -	$ 4,000,000	**$ -**
Cost of revenue	(800,000)	-	(1,600,000)	**-**
Gross Profit	1,200,000	-	2,400,000	-
Operating Expenses:				
Research and development	3,616,382	2,915,250	7,864,108	6,549,537
General and administrative	2,347,191	2,104,163	4,647,518	3,940,945
Total Operating Expenses	5,963,573	5,019,413	12,511,626	10,490,482
Loss From Operations	(4,763,573)	(5,019,413)	(10,111,626)	(10,490,482)
Other Income (Expense):				
Small Business Administration Economic				
Injury Disaster Grant	-	10,000	-	10,000
Interest expense	(78,047)	(6,351)	(83,195)	(10,032)
Interest income	220	199	1,754	24,039

Net Loss	$ (4,841,400)	$ (5,015,565)	$(10,193,067)	$(10,466,475)
Net Loss Per Share - Basic and Diluted	$ (0.19)	$ (0.25)	$ (0.40)	$ (0.56)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	25,927,303	19,821,215	25,630,572	18,563,864

Source: Eyenovia, Inc.